Gregory D. Miller
Sarah C. Mitchell
PODVEY, MEANOR, CATENACCI,
HILDNER, COCOZIELLO & CHATTMAN,
A Professional Corporation
One Riverfront Plaza, Suite 800
Newark, New Jersey 07102
Attorneys for Defendants
Sun Pharmaceutical Industries Ltd.,
Sun Pharma Global Inc.,
Sun Pharma Global FZE,
Sun Pharma USA,
Sun Pharmaceutical Industries, Inc., and
Caraco Pharmaceutical Laboratories, Ltd.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

OTSUKA PHARMACEUTICAL CO., LTD., Plaintiff, v. SUN PHARMACEUTICAL INDUSTRIES LTD., SUN PHARMA GLOBAL INC., SUN PHARMA GLOBAL FZE, SUN PHARMA USA, SUN PHARMACEUTICALS INDUSTRIES, INC. and CARACO PHARMACEUTICAL LABORATORIES, LTD., Defendants.	Civil Action No.: 14-cv-6397-JBS-KMW

ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS OF DEFENDANTS SUN PHARMACEUTICAL INDUSTRIES LTD., SUN PHARMA GLOBAL INC., SUN PHARMA GLOBAL FZE, AND SUN PHARMACEUTICAL INDUSTRIES, INC.

Defendants Sun Pharmaceutical Industries Ltd. ("Sun Ltd."), Sun Pharma Global Inc., Sun Pharma Global FZE, Sun Pharma USA, Sun Pharmaceuticals Industries, Inc., and Caraco Pharmaceutical Laboratories, Ltd. (collectively, "Sun Defendants" or "Defendants"), by their attorneys, answer the Complaint of Plaintiff Otsuka Pharmaceutical Co., Ltd. ("Otsuka" or

"Plaintiff") as follows, wherein paragraph numbers 1-31 correspond to those in the Complaint. Defendants deny all of the allegations of the Complaint not expressly admitted below.

THE PARTIES

1. Otsuka is a corporation organized and existing under the laws of Japan with its corporate headquarters at 2-9 Kanda Tsukasa-machi, Chiyoda-ku, Tokyo, 101-8535, Japan. Otsuka is engaged in the research, development, manufacture and sale of pharmaceutical products.

Answer to Paragraph 1

Defendants are without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 1 and therefore deny the same.

2. Upon information and belief, Sun Ltd. is a corporation organized and existing under the laws of India, having its principal place of business at Acme Plaza, Andheri-Kurla Road, Andheri (E), Mumbai, 400 059, India.

Answer to Paragraph 2

Admitted.

3. Upon information and belief, Sun Pharma Global Inc. is a corporation organized and existing under the laws of the British Virgin Islands, and maintains a post office box at International Trust Building, P.O. Box No. 659, Road Town, Tortola, British Virgin Islands. Upon information and belief, Sun Pharma Global Inc. is a wholly-owned subsidiary of Sun Ltd.

Answer to Paragraph 3

Admitted.

4. Upon information and belief, Sun Pharma Global FZE is a corporation organized and existing under the laws of the United Arab Emirates, having a principal place of business at Office # 43, Block Y, SAIF-Zone (Sharjah Airport International Free Zone), Sharjah, United Arab Emirates. Upon information and belief, Sun Pharma Global FZE is a wholly-owned subsidiary of Sun Pharma Global Inc.

Answer to Paragraph 4

Admitted.

5. Upon information and belief, Sun USA is a wholly-owned subsidiary of Sun Ltd., with its principal place of business at 1150 Elijah McCoy Drive, Detroit, MI, 48202.

Answer to Paragraph 5

Defendants deny the allegations in Paragraph 5. Defendants state that Sun Pharma USA does not exist.

6. Upon information and belief, Sun Pharmaceuticals Industries, Inc. is a corporation organized and existing under the laws of Michigan, having a facility at 270 Prospect Plains Rd., Cranbury, NJ 08512. Upon information and belief, Sun Pharmaceuticals Industries, Inc. is a wholly-owned subsidiary of Sun Ltd. Upon information and belief, Sun Pharmaceuticals Industries, Inc. is the U.S. entity of Sun Ltd. Upon information and belief, Sun Pharmaceuticals Industries, Inc. is an authorized agent of Sun Pharma Global FZE.

Answer to Paragraph 6

Defendants admit that Sun Pharmaceutical Industries, Inc. is a Michigan corporation, having a facility at 270 Prospect Plains Road, Cranbury, NJ 08512, and is a wholly-owned subsidiary of Sun Pharmaceutical Industries Ltd. Defendants deny the remaining allegations in Paragraph 6.

7. Upon information and belief, Caraco is a corporation organized and existing under the laws of Michigan, having a facility at 270 Prospect Plains Rd., Cranbury, NJ 08512. Upon information and belief, Caraco is a wholly-owned subsidiary of Sun Ltd. Upon information and belief, Caraco is an authorized agent of Sun Pharma Global FZE. Upon information and belief, Caraco may also be doing business as Sun Pharmaceutical Industries, Inc.

Answer to Paragraph 7

Defendants deny the allegations in Paragraph 7. Defendants state that Caraco Pharmaceutical Laboratories, Ltd. does not exist.

NATURE OF THE ACTION

8. This is an action for infringement of U.S. Patent No. 8,759,350 ("the '350 patent"), arising under the United States patent laws, Title 35, United States Code, § 100 *et seq.*, including 35 U.S.C. §§ 271 and 281. This action relates to Sun Pharma Global FZE's filing of an Abbreviated New Drug Application ("ANDA") under Section 505(j) of the Federal Food, Drug and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration

("FDA") approval to manufacture, use, sell and offer to sell generic pharmaceutical products ("Sun Pharma Global FZE's generic products") before the expiration of the asserted patent.

Answer to Paragraph 8

Paragraph 8 asserts legal conclusions for which no answer is required. To the extent an answer may be required, Defendants admit that Otsuka's Complaint purports to state a claim for infringement of U.S. Patent Nos. 8,759,350 ("the '350 patent") relating to Sun Pharma Global FZE's filing of an ANDA for approval to market a generic product ("Sun's ANDA Product"). Defendants deny the remaining allegations in Paragraph 8.

JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

Answer to Paragraph 9

Paragraph 9 asserts legal conclusions for which no answer is required. To the extent an answer may be required, Defendants admit that this Court has subject matter jurisdiction over Otsuka's claims asserted under 35 U.S.C. § 271(e)(2)(A), and deny the remaining allegations of Paragraph 9.

10. Upon information and belief, this Court has jurisdiction over Sun Ltd. Sun Ltd. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Sun Ltd., directly or through its wholly-owned subsidiaries, including Sun Pharma Global Inc., Sun Pharma Global FZE, Sun USA, Sun Pharmaceuticals Industries, Inc. and Caraco, manufactures, markets, imports and sells generic drugs throughout the United States and in this judicial district. Sun Ltd. has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

Answer to Paragraph 10

Paragraph 10 asserts legal conclusions for which no answer is required. To the extent an answer may be required, Defendants admit to personal jurisdiction with respect to Sun Pharmaceutical

Industries Ltd. in this Court solely for purposes of this action, and deny the remaining allegations in Paragraph 10.

11. Upon information and belief, this Court has jurisdiction over Sun Pharma Global Inc. Upon information and belief, Sun Pharma Global Inc. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Sun Pharma Global Inc., directly or through its parent, subsidiaries, affiliates and/or agents, including Sun Ltd., Sun Pharma Global FZE, Sun USA, Sun Pharmaceuticals Industries, Inc. and Caraco, manufactures, markets, imports and sells generic drugs throughout the United States and in this judicial district. Sun Pharma Global Inc. has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

Answer to Paragraph 11

Paragraph 11 asserts legal conclusions for which no answer is required. To the extent an answer may be required, Defendants admit to personal jurisdiction with respect to Sun Pharma Global Inc. in this Court solely for purposes of this action, and deny the remaining allegations in Paragraph 11.

12. Upon information and belief, this Court has jurisdiction over Sun Pharma Global FZE. Sun Pharma Global FZE is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Sun Pharma Global FZE, directly or through its parent, subsidiaries, affiliates and/or agents, including Sun Ltd., Sun Pharma Global Inc., Sun USA, Sun Pharmaceuticals Industries, Inc. and Caraco, manufactures, markets, imports and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Sun Pharma Global FZE purposefully has conducted and continues to conduct business, directly or through its parent, subsidiaries, affiliates and/or agents, including Sun Ltd., Sun Pharma Global Inc., Sun USA, Sun Pharmaceuticals Industries, Inc. and Caraco, in this judicial district and this judicial district is a likely destination of Sun Pharma Global FZE's generic products. Sun Pharma Global FZE's authorized agent in this judicial district is John L. Dauer Jr., Esq., Chief Patent Counsel, Sun Pharmaceutical Industries, Inc., 270 Prospect Plains Rd., Cranbury, NJ 08512. Additionally, Sun Pharma Global FZE has availed itself of the laws of New Jersey by, at least, indicating that an offer to access confidential information relating to Sun Pharma Global FZE's ANDA No. 78-614 "shall be governed by the laws of the State of New Jersey." Upon information and belief, Sun Pharma Global FZE has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

Answer to Paragraph 12

Paragraph 12 asserts legal conclusions for which no answer is required. To the extent an answer may be required, Defendants admit to personal jurisdiction with respect to Sun Pharma Global FZE in this Court solely for purposes of this action, and deny the remaining allegations in Paragraph 12.

13. Upon information and belief, this Court has jurisdiction over Sun USA. Sun USA is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Sun USA, directly or through its parent, subsidiaries, affiliates and/or agents, including Sun Ltd., Sun Pharma Global Inc., Sun Pharma Global FZE, Sun Pharmaceuticals Industries, Inc. and Caraco, manufactures, markets, imports and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Caraco's website states:

> Sun Pharma USA is the US arm of Sun Pharmaceutical Industries, Ltd. ("Sun Pharma"), a leading pharmaceutical company in India. Sun Pharma USA consists of Sun Pharma subsidiaries Caraco Pharmaceutical Laboratories, Ltd. with locations in the Detroit, MI area, New Jersey and Ohio . . . .

See http://www.caraco.com/aspx/CorporateProfile.aspx (emphasis added) (accessed June 4, 2014).

Answer to Paragraph 13

Paragraph 13 asserts legal conclusions for which no answer is required. To the extent an answer may be required, Defendants deny the allegations in Paragraph 13. Defendants state that Sun Pharma USA does not exist.

14. Upon information and belief, this Court has jurisdiction over Sun Pharmaceuticals Industries, Inc. Sun Pharmaceuticals Industries, Inc. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Sun Pharmaceutical Industries, Inc., directly or through its parent, subsidiaries, affiliates and/or agents, including Sun Ltd., Sun Pharma Global Inc., Sun Pharma Global FZE, Sun USA and Caraco, manufactures, markets, imports and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Caraco's website states that Sun Pharmaceuticals Industries, Inc. "markets and distributes generic pharmaceuticals to the nation's largest wholesalers" and that it "is a vertically integrated manufacturer with the flexibility to develop and manufacture both in the U.S. and overseas." See

http://www.caraco.com/aspx/CorporateProfile.aspx (accessed Sept. 29, 2014). In addition, Sun Pharmaceuticals Industries, Inc. maintains "a focus on creating value with quality generic pharmaceuticals with strategic focus on the needs of U.S. health care system." *Id.* Sun Pharmaceuticals Industries, Inc. is an authorized agent for Sun Pharma Global FZE in connection with ANDA No. 78-614. Upon information and belief, Sun Pharmaceuticals Industries, Inc. is registered in the State of New Jersey as a drug manufacturer and wholesaler, with Registration No. 5003437. Upon information and belief, Sun Pharmaceuticals Industries Inc. has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

Answer to Paragraph 14

Paragraph 14 asserts legal conclusions for which no answer is required. To the extent an answer may be required, Defendants admit to personal jurisdiction with respect to Sun Pharmaceutical Industries, Inc. solely for purposes of this action, and deny the remaining allegations in Paragraph 14.

15. Upon information and belief, this Court has jurisdiction over Caraco. Caraco is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Caraco, directly or through its parent, subsidiaries, affiliates and/or agents, including Sun Ltd., Sun Pharma Global, Inc., Sun Pharma Global FZE, Sun USA and Sun Pharmaceuticals Industries, Inc., manufactures, markets, imports and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Caraco is an authorized agent for Sun Pharma Global FZE in connection with ANDA No. 78-614. Upon information and belief, Caraco has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

Answer to Paragraph 15

Paragraph 15 asserts legal conclusions for which no answer is required. To the extent an answer may be required, Defendants deny the allegations in Paragraph 15. Defendants state that Caraco Pharmaceutical Laboratories, Ltd. does not exist.

16. Upon information and belief, the Defendants hold themselves out as a unitary entity for purposes of manufacturing, marketing, selling and distributing generic pharmaceutical products.

Answer to Paragraph 16

Paragraph 16 asserts legal conclusions for which no answer is required. To the extent an answer may be required, Defendants deny the allegations in Paragraph 16.

17. Upon information and belief, the Defendants work in concert with each other with respect to the regulatory approval, manufacturing, marketing, sale and distribution of generic pharmaceutical products throughout the United States, including in this judicial district.

Answer to Paragraph 17

Paragraph 17 asserts legal conclusions for which no answer is required. To the extent an answer may be required, Defendants deny the allegations in Paragraph 17.

18. Upon information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and § l400(b).

Answer to Paragraph 18

Paragraph 18 asserts legal conclusions for which no answer is required. To the extent an answer may be required, Defendants admit to proper venue in this judicial district with respect to Sun Pharmaceutical Industries Ltd., Sun Pharma Global Inc., Sun Pharma Global FZE, and Sun Pharmaceuticals Industries, Inc., solely for purposes of this action, and deny the remaining allegations in Paragraph 18.

FIRST COUNT FOR PATENT INFRINGEMENT

19. The U.S. Patent and Trademark Office ("PTO") issued the '350 patent on June 24, 2014, entitled "Carbostyril Derivatives and Serotonin Reuptake Inhibitors for Treatment of Mood Disorders." A copy of the '350 patent is attached as Exhibit A.

Answer to Paragraph 19

Paragraph 19 asserts legal conclusions for which no answer is required. To the extent an answer may be required, Defendants admit that the face of the '350 patent bears the title "Carbostyril Derivatives and Serotonin Reuptake Inhibitors for Treatment of Mood Disorders" and states that

it was issued June 24, 2014, and that Exhibit A to the Complaint purports to be a copy of the '350 patent. Defendants are without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 19 and therefore deny the same.

20. Otsuka is the owner of the '350 patent by virtue of assignment.

Answer to Paragraph 20

Paragraph 20 asserts legal conclusions for which no answer is required. To the extent an answer may be required, Defendants admit that the face of the '350 patent identifies Otsuka as the assignee of the '350 patent. Defendants are without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 20 and therefore deny the same.

21. The '350 patent expires on March 2, 2027, subject to any supplemental patent term adjustment.

Answer to Paragraph 21

Paragraph 21 asserts legal conclusions for which no answer is required. To the extent an answer may be required, Defendants admit that the FDA's Orange Book states that the '350 patent expires on March 2, 2027. Defendants are without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 21 and therefore deny the same.

22. The '350 patent is directed to and claims, *inter alia*, pharmaceutical compositions and methods of treatment.

Answer to Paragraph 22

Paragraph 22 asserts legal conclusions for which no answer is required.

23. Otsuka is the holder of New Drug Application ("NDA") No. 21-436 for aripiprazole tablets, which the FDA approved on November 15, 2002.

Answer to Paragraph 23

Paragraph 23 asserts legal conclusions for which no answer is required. To the extent an answer may be required, Defendants admit that the FDA's Orange Book lists Otsuka as the applicant for NDA No. 21-436 for aripiprazole tablets. Defendants are without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 23 and therefore deny the same.

24. Otsuka lists the '350 patent in Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for NDA No. 21-436.

Answer to Paragraph 24

Paragraph 24 asserts legal conclusions for which no answer is required. To the extent an answer may be required, Defendants admit that the FDA's Orange Book currently lists the '350 patent for NDA No. 21-436. Defendants are without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 24 and therefore deny the same.

25. Otsuka markets aripiprazole tablets in the United States under the trademark Abilify®.

Answer to Paragraph 25

Defendants are without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 25 and therefore deny the same.

26. Upon information and belief, Sun Pharma Global FZE submitted ANDA No. 78614 to the FDA, under Section 505(j), seeking approval to manufacture, use, sell and offer to sell Sun Pharma Global FZE's generic products in the United States.

Answer to Paragraph 26

Defendants admit that ANDA No. 78-614 was submitted to the FDA by or on behalf of Sun Pharmaceutical Industries Ltd. under 21 U.S.C. § 355(j), seeking approval to manufacture, use, sale, offer to sell, and import aripiprazole tablets in the United States. Defendants deny the remaining allegations in Paragraph 26.

27. Otsuka received a letter from an authorized agent for Sun Pharma Global FZE, Sun Pharmaceuticals Industries, Inc., dated August 22, 2014, ("Sun Pharma Global FZE's Letter") purporting to include a Notice of Certification for ANDA No. 78-614 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95 as to the '350 patent.

Answer to Paragraph 27

Paragraph 27 contains legal conclusions for which no answer is required. To the extent an answer may be required, Defendants admit that a Notice of Certification for ANDA No. 78-614 dated August 22, 2014, was served on Otsuka on behalf of Sun Pharma Global FZE by its authorized agent (*i.e.*, John L. Dauer, Jr., Esq., Chief Patent Counsel of Sun Pharmaceutical Industries, Inc.), under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95 as to the '350 patent, and that Otsuka has admitted receipt of that letter.

28. Sun Pharma Global FZE's Letter states that "the established name of the proposed drug product that is the subject of the SUN ANDA is Aripiprazole Tablets."

Answer to Paragraph 28

Paragraph 28 contains legal conclusions for which no answer is required. To the extent an answer may be required, admitted.

29. Upon information and belief, Sun Pharma Global FZE's generic products will, if approved and marketed, infringe at least one claim of the '350 patent.

Answer to Paragraph 29

Denied.

30. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Sun Pharma Global FZE has infringed at least one claim of the '350 patent by submitting, or causing to be submitted to the FDA, ANDA No. 78-614 seeking approval to manufacture, use, sell and offer to sell Sun Pharma Global FZE's generic products before the expiration date of the '350 patent.

Answer to Paragraph 30

Denied.

31. Upon information and belief, Sun Pharma Global FZE's actions relating to ANDA No. 78-614 complained of herein were done with the cooperation, participation and assistance, and for the benefit, of the Defendants.

Answer to Paragraph 31

Denied.

DEFENDANTS' ANSWER TO REQUEST FOR RELIEF

Defendants deny that Otsuka is entitled to the judgment or any other relief requested in Paragraphs 1 to 6 of Otsuka's request for relief in the "Wherefore" clause of the Complaint.

DEFENDANTS' AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth above, without admitting any allegation in the Complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on Otsuka, Defendants assert the following affirmative defenses:

FIRST AFFIRMATIVE DEFENSE
(NON-INFRINGEMENT)

32. The manufacture, use, sale, offer for sale, and/or importation of the product that is the subject of Defendants' ANDA No. 78-614 does not infringe and will not infringe, directly or indirectly, any valid and enforceable claim of the '350 patent, either literally or under the doctrine of equivalents.

SECOND AFFIRMATIVE DEFENSE
(INVALIDITY)

33. Each and every claim of the '350 patent is invalid under 35 U.S.C. § 101, *et seq.* including, *inter alia*, §§ 102, 103, and/or 112, for obviousness-type double patenting, and/or other judicially-created bases for invalidation.

THIRD AFFIRMATIVE DEFENSE
(FAILURE TO STATE A CLAIM)

34. Otsuka's Complaint, in whole or in part, fails to state a claim upon which relief can be granted including, *inter alia*, any claims against Defendants Sun Pharma USA and Caraco Pharmaceutical Laboratories, Ltd. and any claims for exceptional case under 35 U.S.C. §§ 285 and/or 271(e)(4).

FOURTH AFFIRMATIVE DEFENSE
(LACK OF SUBJECT MATTER JURISDICTION)

35. This Court lacks subject matter jurisdiction to the extent Otsuka's claims of infringement are not limited to patent claims that cover only the product which is the subject of Otsuka's NDA No. 21-436 or methods of use of said product.

FIFTH AFFIRMATIVE DEFENSE
(NO COSTS UNDER 35 U.S.C. § 288)

36. Plaintiffs are barred by 35 U.S.C. § 288 from recovering any of their costs in this action.

DEFENDANTS' COUNTERCLAIMS

Counterclaim Plaintiffs Sun Pharmaceutical Industries Ltd. ("Sun Ltd."), Sun Pharma Global Inc., Sun Pharma Global FZE, Sun Pharmaceutical Industries, Inc. (collectively "Counterclaim Plaintiffs") for their counterclaims against Otsuka Pharmaceutical Co., Ltd. ("Otsuka" or "Counterclaim Defendant") allege and aver as follows:

THE PARTIES

1. Counterclaim Plaintiff Sun Ltd. is a corporation organized and existing under the laws of India, having a place of business at Acme Plaza, Andheri - Kurla Road, Andheri (E), Mumbai, 400 059, India.

2. Counterclaim Plaintiff Sun Pharma Global Inc. is a corporation organized and existing under the laws of the British Virgin Islands, with a mailing address at International Trust Building, P.O. Box No. 659, Road Town, Tortola, British Virgin Islands.

3. Counterclaim Plaintiff Sun Pharma Global FZE is a corporation organized and existing under the laws of the United Arab Emirates, having a place of business at Office # 43, Block Y, SAIF-Zone (Sharjah Airport International Free Zone), Sharjah, United Arab Emirates.

4. Counterclaim Plaintiff Sun Pharmaceutical Industries, Inc. is Michigan corporation, having a facility at 270 Prospect Plains Road, Cranbury, NJ 08512.

5. Upon information and belief, Counterclaim Defendant Otsuka is a corporation organized and existing under the laws of Japan with its corporate headquarters at 2-9 Kanda Tsukasa-machi, Chiyoda-ku, Tokyo, 101-8535, Japan.

JURISDICTION AND VENUE

6. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

7. This Court has subject matter jurisdiction over these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a) and under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

8. This Court has personal jurisdiction over Otsuka because Otsuka has availed itself of the rights and privileges of this forum, and subjected itself to the jurisdiction of this forum, by

suing Counterclaim Plaintiffs in this District, and/or because, upon information and belief, Otsuka conducts continuous and substantial business in this District.

9. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and 1400(b).

FACTUAL BACKGROUND

10. Upon information and belief, U.S. Patent No. 8,759,350 ("the '350 patent"), entitled "Carbostyril Derivatives and Serotonin Reuptake Inhibitors for Treatment of Mood Disorders," was issued on June 24, 2014.

11. The '350 patent is listed in the FDA's Electronic Orange Book for aripiprazole tablets (Abilify®).

12. Otsuka claims to have the right to enforce the '350 patent.

13. Otsuka claims to be the current holder of New Drug Application ("NDA") No. 21-436 (the "Abilify® NDA") for aripiprazole tablets (Abilify®).

14. Abbreviated New Drug Application No. 78-614 ("ANDA No. 78-614" or "Sun's ANDA") was submitted to the FDA under 21 U.S.C. § 355(j) on behalf of one or more Counterclaim Plaintiffs, to obtain FDA approval for an aripiprazole tablet product ("Sun's ANDA Product") for the activities stated in Sun's ANDA.

15. Counterclaim Plaintiffs included in Sun's ANDA, in good faith and with an objective, reasonable basis, a paragraph IV certification for the '350 patent.

THE ACTUAL CONTROVERSY

16. Otsuka filed the present Complaint against Counterclaim Plaintiffs in this District alleging infringement of the '350 patent.

17. An actual, substantial, and continuing justiciable case or controversy exists between Counterclaim Plaintiffs and Otsuka regarding the non-infringement and invalidity of the '350 patent.

FIRST COUNTERCLAIM
(DECLARATORY JUDGMENT OF NON-INFRINGEMENT)

18. Counterclaim Plaintiffs repeat, reallege, and incorporate by reference the allegations of paragraphs 1-17 of these Counterclaims as if fully set forth herein.

19. This counterclaim is for a declaration that Counterclaim Plaintiffs have not infringed, directly or indirectly, and do not and will not infringe, directly or indirectly, any valid and enforceable claim of the '350 patent, either literally or under the doctrine of equivalents.

20. This counterclaim is for a declaration that the manufacture, use, sale, and offer for sale in the United States, and importation into the United States, of Sun's ANDA Product does not and will not infringe, directly or indirectly, any valid and enforceable claim of the '350 patent, either literally or under the doctrine of equivalents.

SECOND COUNTERCLAIM
(DECLARATORY JUDGMENT OF INVALIDITY

21. Counterclaim Plaintiffs repeat, reallege, and incorporate by reference the allegations of paragraphs 1-20 of these Counterclaims as if fully set forth herein.

22. This counterclaim is for a declaration that each and every claim of the '350 patent is invalid under 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 102, 103, and/or 112, for obviousness-type double patenting, and/or other judicially-created bases for invalidation.

DEFENDANTS'/COUNTERCLAIM PLAINTIFFS' REQUEST FOR RELIEF

Wherefore, Counterclaim Plaintiffs Sun Pharmaceutical Industries Ltd. ("Sun Ltd."), Sun Pharma Global Inc, Sun Pharma Global FZE, and Sun Pharmaceuticals Industries, Inc. ("Counterclaim Plaintiffs"; and together with Sun Pharma USA and Caraco Pharmaceutical Laboratories, Ltd., "Defendants") respectfully request that:

(a) Judgment be entered in favor of Defendants on Otsuka's Complaint, that the Complaint against Defendants be dismissed with prejudice, and that Otsuka take nothing thereby;

(b) Judgment be entered that the manufacture, use, offer to sell, and/or sale in the United States, or importation into the United States, of the product that is the subject of Sun's ANDA No. 78-614 does not and will not infringe, directly or indirectly, any valid and enforceable claim of the '350 patent, either literally or under the doctrine of equivalents;

(c) Judgment be entered that Defendants have not infringed, directly or indirectly, any valid and enforceable claim of the '350 patent, either literally or under the doctrine of equivalents;

(d) Judgment be entered that each and every claim of the '350 patent is invalid;

(e) The Court permanently enjoin Otsuka and its assigns, successors, officers, agents, servants, employees, attorneys, licensees, and any person who acts in concert or participation with any of them, from asserting that the manufacture, use, offer to sell, and/or sale in the United States, or importation into the United States, of the product that is the subject of ANDA No. 78-614 has infringed, infringes, or will infringe, any claim of the '350 patent, directly or indirectly, either literally or under the doctrine of equivalents;

(f) This case be deemed an exceptional case with Defendants as the prevailing party under 35 U.S.C. § 285;

(g) The Court award Defendants their attorneys' fees pursuant to 35 U.S.C. § 285, other statutes or rules, or the general power of the Court;

(h) The Court award Defendants their costs; and

(i) The Court award Defendants such other and further relief as it may deem just and proper.

Dated: December 11, 2014

Respectfully submitted,

s/ Gregory D. Miller

Gregory D. Miller
Sarah C. Mitchell
PODVEY, MEANOR, CATENACCI,
HILDNER, COCOZIELLO & CHATTMAN,
A Professional Corporation
One Riverfront Plaza, Suite 800
Newark, New Jersey 07102

Attorneys for Defendants
Sun Pharmaceutical Industries Ltd.,
Sun Pharma Global Inc.,
Sun Pharma Global FZE,
Sun Pharma USA,
Sun Pharmaceutical Industries, Inc., and
Caraco Pharmaceutical Laboratories, Ltd.

OF COUNSEL:
Martin B. Pavane
Julia S. Kim
Darren S. Mogil
COZEN O'CONNOR
277 Park Avenue
New York, New York 10172
(212) 883-4900
mpavane@cozen.com
jkim@cozen.com
dmogil@cozen.com

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